IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Policky et al.
Title:	HUMAN CYSTEINYL LEUKOTRIENE RECEPTORS
Application No.:	09/980,049
Filing Date:	11/28/2001
Examiner:	Ulm, John D.
Art Unit:	1649

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Deborah A. Kocorowski (Printed Name)

Deborah A. Kocorowski (Signature)

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Alexandria, VA 22313-1450

REQUEST FOR PRE-APPEAL BRIEF REVIEW

This communication is submitted in response to the final Office Action dated September 22, 2005, and the Advisory Action dated January 27, 2006. A Notice of Appeal is included herewith.

The Applicants request Pre-Appeal Brief Review and reconsideration of the application in view of the remarks which follow.

Remarks begin on page 2 of this document.

REMARKS

I. Summary of the Objections and Rejections

Claims 1-7, 9, 11, 16, 17, 19, 22, 26, and 57-61 are currently pending in this application. The claims were objected to and rejected in a final Office Action dated September 22, 2005. The Advisory Action dated January 27, 2006, indicates that the Applicants' request for reconsideration did not place the application in condition for allowance.

All of the objections and rejections are based on the contention that the present application and its priority application (U.S. provisional application no. 60/199,084) disclose that the polypeptide of SEQ ID NO:1 is a human cysteinyl leukotriene receptor.

II. Assertion that SEQ ID NO:1 is a Human Cysteinyl Leukotriene Receptor

The present application generally relates to G-Protein Coupled Receptors (*i.e.*, "GPCRs" or "GCRECs"). In fact, the application as filed is entitled "G-Protein Coupled Receptors." In the specification, the polypeptide of SEQ ID NO:1 is referred to as "G-Protein Coupled Receptor 1" or "GCREC-1." At paragraph [0130], the specification states that "[t]ogether, Tables 2 and 3 summarize the properties of polypeptides of the invention, and ***these properties establish that the claimed polypeptides are G-protein coupled receptors***." Therefore, it is undisputable that SEQ ID NO:1 is asserted to be a human G-Protein Coupled Receptor. However, the specification provides even further disclosure with respect to the function of the polypeptide of SEQ ID NO:1 and indicates that the polypeptide of SEQ ID NO:1 functions as a G-coupled protein receptor for cysteinyl leukotrienes.

At paragraph [0004], the specification states that "GPCRs include receptors for...lipid mediators of inflammation (e.g.,...***leukotrienes***)" (emphasis added). Further, the specification states at paragraph [0130] that "Tables 2 and 3 ***summarize the properties of polypeptides of the invention***" (emphasis added). As such, the Applicants have asserted that Table 2 and 3 ***summarize the properties of the polypeptide of SEQ ID NO:1***. Table 2 provides:

TABLE 2

Polypeptide SEQ ID NO:	Incyte Polypeptide ID	GenBank ID NO:	Probability Score	GenBank Homolog
1	5628963CD1	g10442008	0	Cysteinyl leukotriene receptor CYSLT2 [*Homo sapiens*] (Heise, C. E. et al. (2000) J. Biol. Chem. 275: 30531–30536)

Table 2 shows that "Cysteinyl leukotriene receptor CYSLT2 [*Homo sapiens*]" is the nearest GenBank homolog for the polypeptide of SEQ ID NO:1 and that there is a zero (0) probability score for a match by BLAST analysis between "Cysteinyl leukotriene receptor CYSLT2 [*Homo sapiens*]" and the polypeptide of SEQ ID NO:1. In Table 2, a low probability score is indicative of a low probability of having obtained a match ***by chance***, and accordingly, a probability score of zero (0) means that there is zero probability of having obtained the match by chance. Therefore, the only reasonable interpretation of the disclosure in the specification, reading paragraphs [0004] and [0130] and Table 2 together, is that SEQ ID NO:1 is asserted to be a human G-Protein Coupled Receptor for cysteinyl leukotrienes. At Table 3, the specification indicates that SEQ ID NO:1 includes "Signature Sequences, Domains and Motifs," which are characteristic of cysteinyl leukotriene receptors and supports the explicit assertion that SEQ ID NO:1 is a human cysteinyl leukotriene receptor.

Provisional Application No. 60/199,084 ("the '084 Application") (copy previously provided) includes substantially similar disclosure as the present application with respect to the polypeptide of SEQ ID NO:1. At page 5, lines 1-2, the '084 Application discloses that SEQ ID NO:1 is referred to as "G-Protein Coupled Receptor 1" or "GCREC-1." At page 2, lines 4-10, the '084 Application states that "GPCRs include receptors for...lipid mediators of inflammation (e.g.,...***leukotrienes***)." Table 2 of the '084 Application provides:

Table 2

Polypeptide SEQ ID NO:	Incyte Polypeptide ID	GenBank ID NO:	Probability Score	GenBank Homolog
1	5628963CD1	g5353887	2.2e-54	Cysteinyl leukotriene LTD4 receptor [Homo sapiens]
2	1453124CD1	g5525078	1.0e-134	Seven transmembrane receptor [Rattus norvegicus]

As such, Table 2 shows that "Cysteinyl leukotriene LTD4 receptor [Homo sapiens]" is the nearest GenBank homolog for the polypeptide of SEQ ID NO:1 and indicates that there is very low probability score for a match by BLAST analysis between "Cysteinyl leukotriene LTD4 receptor [Homo sapiens]" and the polypeptide of SEQ ID NO:1 (*i.e.*, a 2.2×10^{-54} probability of having obtained the match by chance). At Table 3, the specification of the '084 Application indicates that SEQ ID NO:1 includes "Signature Sequences, Domains and Motifs," which are characteristic of cysteinyl leukotriene receptors and supports the explicit assertion that SEQ ID NO:1 is a human cysteinyl leukotriene receptor.

Therefore, the specifications of the present application and the '084 Application include explicit assertions that the polypeptide of SEQ ID NO:1 is a human G-Protein Coupled Receptor for cysteinyl leukotrienes.

III. Objection – 35 U.S.C. § 132, "New Matter"

The amendment filed on July 13, 2005, was objected to for allegedly introducing new matter into the disclosure. In particular, the Title, which recites "HUMAN CYSTEINYL LEUKOTRIENE RECEPTORS," and the claim limitation "wherein the polypeptide has cysteinyl leukotriene receptor activity" are alleged to be "new matter." As indicated above, the specification as filed explicitly asserts that SEQ ID NO:1 is a human cysteinyl leukotriene receptor.

IV. Rejection – 35 U.S.C. § 101, "Utility"

Claims 1-7, 9, 11, 16, 17, 19, 22, 26, and 57-61 stand rejected under 35 U.S.C. § 101 allegedly "because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility." As indicated above, the specification explicitly asserts that SEQ ID NO:1 is a human cysteinyl leukotriene receptor. Others have confirmed that SEQ ID NO:1 is a cysteinyl leukotriene receptor, referred to as "human cysteinyl leukotriene 2 receptor." *See, e.g.,* Heise *et al.*, *Characterization of the Human Cysteinyl Leukotriene 2 Receptor*, J. BIOL. CHEM. (September 2000), Vol. 275, No. 39, pp 30531-30536, [hereinafter "Heise"] (copy previously provided). Therefore, the asserted utility is credible.

Furthermore, Heise indicates that cysteinyl leukotriene receptors are known to mediate contractile and inflammatory actions of cysteinyl leukotriene ligands. In particular, cysteinyl leukotriene receptors are known to mediate bronchoconstrictive and inflammatory actions in the lungs. Therefore, the claimed subject matter has a credible, well known, specific and substantial utility.

V. Rejection – 35 U.S.C. § 112, first paragraph, "Enablement"

Claims 1-7, 9, 11, 16, 17, 19, 22, 26, and 57-61 stand rejected under 35 U.S.C. § 112, first paragraph, allegedly "as failing to adequately teach how to use the invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101." For the reasons stated above with respect to rejection under 35 U.S.C. § 101, the specification asserts a utility for the claimed subject matter and adequately teaches how to make and use the claimed invention.

VI. Rejection – 35 U.S.C. § 112, first paragraph, "Written Description"

Claims 1- 7, 9, 11, 16, 17, 19, 22, 26, and 57-61 stand rejected under 35 U.S.C. § 112, first paragraph, allegedly "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." In particular, the Examiner asserts that the application does not "provided a written description of a polypeptide having the amino acid sequence presented in SEQ ID NO:1 and 'cysteinyl leukotriene activity.'" Further, the Examiner asserts that "the phrase 'cysteinyl leukotriene receptor activity' is without support in the instant application and a relationship between this activity and SEQ ID NO:1 is a new inventive concept."

As indicated above, the specification explicitly asserts that the polypeptide of SEQ ID NO:1 functions as a human cysteinyl leukotriene receptor. Furthermore, the asserted function is credible and in fact has been confirmed. Therefore, a polypeptide of SEQ ID NO:1 having cysteinyl leukotriene receptor activity is disclosed in the specification and is not a new inventive concept without support in the specification.

VII. Rejection – 35 U.S.C. § 102, "Takasaki et al."

Claims 1-7, 9, 11, 16, 17, 19, 22, 26 and 57-61 stand rejected under 35 U.S.C. § 102(a) as being allegedly anticipated by Takasaki et al., B.B.R.C. 274(2):316-322, (Aug. 2000)" ("Takasaki").

As indicated above, the present application claims the benefit of priority of U.S. provisional Application No. 60/199,084, filed on April 20, 2000. Also as indicated above, the '084 Application includes substantially similar disclosure as the present application with respect to the polypeptide of SEQ ID NO:1. In particular, the '084 Application includes an explicit assertion that the polypeptide of SEQ ID NO:1 is a human G-Protein Coupled Receptor for cysteinyl leukotrienes. Therefore, the '084 Application fully supports the presently claimed subject matter under 35 U.S.C. § 112, and the pending claims are entitled to a priority date at least as of the filing date of the '084 Application (*i.e.*, April 20, 2000), which predates the Takasaki publication.

VIII. Conclusion

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date February 21, 2006 By _____

FOLEY & LARDNER LLP
Customer Number: 22428

M. Scott McBride
Attorney for the Applicants
Registration No. 52,008
Telephone: (414) 297-5529
Facsimile: (414) 297-4900